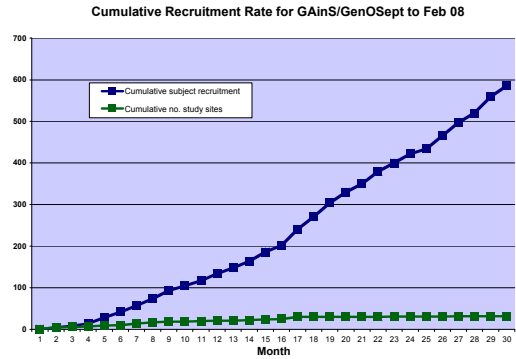


**Dear Colleagues,**

**464 patients in GAinS** By the end of February, 464 patients with faecal peritonitis (195) and community-acquired pneumonia (269) had been recruited to GAinS. Recruitment numbers for GAinS and GenOSept, for individual centres are shown below:

| Site                         | Recruits up to 28.02.08 |
|------------------------------|-------------------------|
| John Radcliffe               | 65                      |
| Royal Berks, Reading         | 58                      |
| Norfolk and Norwich          | 57                      |
| Aberdeen                     | 51                      |
| RVI, Newcastle               | 39                      |
| Southend                     | 33                      |
| Swindon                      | 29                      |
| Chelmsford                   | 29                      |
| Worthing                     | 23                      |
| Royal Sussex, Brighton       | 23                      |
| Frimley Park                 | 21                      |
| St Bart's                    | 20                      |
| Queen Elizabeth, Birmingham  | 19                      |
| Cheltenham                   | 16                      |
| Leicester                    | 14                      |
| Addenbrookes                 | 14                      |
| Wythenshawe                  | 13                      |
| St Jame's, Leeds             | 12                      |
| Jame's Cook, Middlesbro'     | 12                      |
| Kings Lynn                   | 8                       |
| Lewisham                     | 6                       |
| Hope, Salford                | 5                       |
| Ipswich                      | 4                       |
| Chelsea & Westminster        | 4                       |
| Royal Hallamshire, Sheffield | 3                       |
| Cardiff                      | 3                       |
| Homerton                     | 2                       |
| Antrim                       | 2                       |
| Leeds General                | 2                       |
| Medway                       | 0                       |
| King's College               | 0                       |
| UCL/Middlesex                | 0                       |



There was a recruitment peak of 40 patients in January with more than half of these having CAP. A fantastic effort from all the centres and our thanks to all investigators and research nurses for your commitment to the project.

### **New Centres Welcome**

We have another four sites about to 'go live' and look forward to their contribution to these studies. If you know of a colleague who you think would like to join GAinS/GenOSept, have them contact us at: [ICUgeneticresearch@orh.nhs.uk](mailto:ICUgeneticresearch@orh.nhs.uk)

### **1555 patients in**

**GenOSept** Recruitment to GenOSept Europe-wide has exceeded 1555 patients as more countries and centres come on-stream. More than 100 patients are being recruited each month! Almost all GAinS centres in the UK have also joined the GenOSept project and receive 100 euros for every patient recruited to GenOSept/GAinS.

The electronic case report form (eCRF) is available for patients recruited to both GenOSept and GAINs. Log onto the eCRF at: <https://www.genosept.eu/index.ecrf/> Your username and password will be provided by the GenOSept central office. If there are problems getting passwords email Paula Hutton at: [ICUgeneticresearch@orh.nhs.uk](mailto:ICUgeneticresearch@orh.nhs.uk)

The UK continues to lead the European league table below with 383 patients recruited, which represents nearly 25% of the total number.

|                       |            |
|-----------------------|------------|
| Austria               | 1          |
| Belgium               | 185        |
| Czech Republic        | 159        |
| Croatia               | 12         |
| Germany               | 147        |
| Ireland               | 90         |
| Israel                | 14         |
| Italy                 | 108        |
| Poland                | 68         |
| Spain                 | 242        |
| <b>United Kingdom</b> | <b>383</b> |
| Serbia                | 19         |
| Estonia               | 18         |
| France                | 105        |
| Greece                | 4          |

## Reimbursement for GenOSept patients

UK and other European centres have been receiving reimbursement for patients recruited to GenOSept. The first payment is made after the 1<sup>st</sup> 5 patients have been enrolled and from then on payments are made on a quarterly basis.

## Data Quality Assurance (QA)

The joint GAINs/GenOSept projects are being actively subjected to a QA programme to ensure accuracy and

completeness of the eCRF data. Alex Smith and Paula Hutton, based in Oxford, have reviewed hundreds of eCRFs from across the UK and Europe! Errors or omissions create alerts which are used to generate email data queries. More than 2,000 queries have been sent but only about a quarter of these having been resolved so far. Do contact us if anything needs clarification. Please respond to the data queries as soon as possible so that the data set of patients recruited to date can be used in the interim analysis in July/August this year.

## UK Clinical Research Network (UKCRN)

UKCRN has included the GenOSept study into its NIHR Clinical Research Network Portfolio. This means that each study centre may be eligible to claim some funding to support the GenOSept research activity at that site. Please do contact your local Research and Development department to ask if you may be entitled to some financial support from the network to support your work on the GenOSept study. See: <http://www.ukcrn.org.uk/index.html>

## Data analysis strategy

A genome-wide association analysis will be performed on the initial cohort of 1800 GenOSept patients beginning July/August 2008. Replication and fine mapping will be undertaken on a subsequent cohort of 700-800 patients.

Patient recruitment for GenOSept will end at the end of December 2008. Recruitment to GAINs will continue for 2-3 more years.

**GAINs website** Just a reminder of the website for the GAINs study. The URL is: <http://www.ukccg-gains.org/>

This contains information about the study, membership of the group and contact details, as well as links to other websites.

## **UKCCG Meeting**

This years meeting will be held in London in the Summer. We will try to give you as much advanced notice as possible.

**Thanks** We have made great progress with the collections for both GAinS and GenOSept. This is entirely due to the enormous efforts of the Investigators and Research Nurses in each of the UK and European ICUs. Thank you!

**CRF questions** CRF questions and answers can be found on the UKCCG website <http://www.ukccg-gains.org/> – select ‘technical information’, Of course you are welcome to contact us at any time by phone or email with any questions you may have about the studies., please see contact details below.

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